39. The composition of claim 38, wherein said localizing device is selected from the group consisting of a stent, a vascular catheter and a urinary catheter.

Please cancel claims 7-9, 12, 14-16, 18, 21, 26 and 32.

REMARKS

The December 18, 2002 Official Action and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, Applicants note that the requirement for restriction set forth in the August 22, 2002 Official Action has been made final. The cancellation of any claims herein is being done to expedite prosecution of the present application. Such cancellation should not be construed in any way as acquiescence to the position taken by the Exmainer in the December 18, 2002 Official Action. Applicants reserve the right to file one or more continuing applications under 35 U.S.C. §120 on the subject matter of claims canceled or withheld from consideration.

As an additional preliminary matter, the specification has been amended to recite the priority claim set forth in the Declaration when the application was filed. The requisite petition and fee are being forwarded to the USPTO under a separate paper.

The Examiner has rejected claims 1, 3-5, 7-9, 12, 14-16, 18, 21, 28-28, 32 and 33 under 35 U.S.C.§112, first paragraph as allegedly inadequately enabled by the specification as filed.

Claims 14-16 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for the recitation of the phrase "reducing the overall electronegative charge".

Claims 14-16 have been cancelled thereby rendering this rejection moot.

The Examiner has rejected claims 1, 3, 8, 12, 14-16, 21, 26-28, 32 and 33 under 35 U.S.C. §102(a) as allegedly anticipated by Schneider et al.

At page 11 of the Official Action, the Examiner rejects claims 1, 4, 12, 14-16, 21, 26-28, 32, and 33 as allegedly anticipated by Shih et al.

The Examiner has further rejected claims 1, 3, 12, 14, 27, 28, and 33 under §102(b) as allegedly unpatentable over Watanabe et al.

The rejections summarized above constitute the entirety of the rejections raised by the Examiner in the December 18, 2002 Official Action. No other issues are pending in the present application. Applicants respectfully submit that the claims as presently amended are in condition for allowance. Each of the above-noted rejections under 35 U.S.C. §112, first and second paragraphs, §102(a) and §102(b) is, therefore, respectfully traversed.

CLAIMS 1, 3-5, and 27,28, 33 AS AMENDED, AND NEW CLAIMS 34-40, ARE CLEARLY COMMENSURATE IN SCOPE WITH THE ENABLEMENT PROVIDED IN APPLICANTS' SPECIFICATION

The Examiner has rejected claims 1, 3-5, 7-9, 12, 14-16, 18, 21 and 26 under 35 U.S.C. §112, first paragraph on the ground that the enablement provided in the specification is insufficient to support the entire scope of Applicant's claims. It is the Examiner's position that the specification fails to provide the requisite guidance with respect to the selection of agents which would be expected to increase "the cytoskeletal permissiveness for transfection or how such agents would be provided to cells, particularly in vivo".

The claims have been amended to recite that the

molecule (formally agent) is tenascin C and peptides thereof which induce a morphological change in cells contacted with the molecule. Support for this amendment can be found at page 27, lines 25-29 and in Figure 4, panels B, C, and D.

A rejection under 35 U.S.C. §112, first paragraph, based on inadequate enablement is proper only when the rejected claim(s) is (are) of such breadth as to read on subject matter to which the specification is not enabling. In re Borkowski, 164 U.S.P.Q. 642 (CCPA 1970). Moreover, it is settled law that whenever the adequacy of enablement provided by an applicant's specification is challenged, the PTO has the initial burden of giving reasons, supported by the record as a whole, why the specification is not enabling. In re Armbruster, 185 U.S.P.Q. 152 (CCPA 1975). Indeed, a properly supported showing that the disclosure entails undue experimentation is part of the PTO's initial burden under §112, first paragraph. In re Angstadt, 190 U.S.P.Q. 214 (CCPA 1976).

New claims 34-39 are fully enabled by the specification as filed. Support for the new claims can be found at page 16, lines 2-13 and at page 18, lines 13-16.

As the Examiner acknowledges at page 5 of the Official Action, the specification enables enhancing transfection of cells by growing the cells in the presence of tenascin C before during and after transfection. Inasmuch as the claims have been amended to recite that the molecule which enhances transfection is tenascin C, it is respectfully submitted that the §112, first paragraph rejection of the claims 1, 3-5, 27, and 28 as amended is no longer appropriate and should be withdrawn. Likewise the newly added claims recite this feature and thus should also be considered fully enabled by the specification as filed.

CLAIMS 1, 3-5, 27, 28, AND NEW CLAIMS 34-39 ARE NOT ANTICIPATED BY THE DISCLOSURE SCHNEIDER ET AL.

In order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a prior art reference must identically disclose each and every element of the rejected claim(s). In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Applicants respectfully submit that claims 1, 3-5, 27 and 28 are not anticipated by the disclosure in the Schneider et al. reference, which plainly fails to disclose each and every element of the claims as amended and claims dependent therefrom.

The claims have been amended to recite that the molecule which enhances transfection is tenascin C. Schneider et al. disclose the use of a peptide within tenascin C for enhancing expression into alpha-9-beta-1 expressing cells. Tenascin C has more than 25 different receptor binding domains. Using the entire molecule thus provides an advantage over using a specific peptide per se. Nor does the Schneider et al. reference teach that contact with cells with a peptide from Tenascin induces a morphological change. Inasmuch as Schneider et al. do not disclose an identical method, composition or kit, the rejection of the claims as amended under §102(a) is improper and should be withdrawn.

The deficiencies noted above for the Schneider et al reference are likewise applicable to Shih et al. and Watanabe et al. There is no disclosure whatsoever in either of these references relating to the use of tenascin C for enhancing transfection efficiency. Accordingly, the rejection of claims 1, 3-5, 27 and 28, as amended, and new claims 34-39 based on these references is improper and should be withdrawn.

It is respectfully urged that this case be placed in condition for allowance. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone

the undersigned attorney at the phone number give below. In the event a fee is required the Examiner is authorized to charge the deposit account of the undersigned 04-1406.

Respectfully submitted,

DANN, DORFMAN, HERRELL AND SKILLMAN

A Professional Corporation

By 

Kathleen D. Rigaut, Ph.D.

PTO Registration No. 43,047

Telephone: (215) 563-4100

Enclosures: Marked up draft of claims showing amendments thereto.

MARKED UP DRAFT OF AMENDED CLAIMS

(Amended) A method for enhancing the efficiency of delivery of a nucleic acid to a cell, said method comprising

a) providing to said cell a[n agent] molecule [capable of enhancing the cytoskeletal permissiveness of said cell for transfection in an amount effective to enhance said permissiveness] which causes morphology of a cell to be transfected to change from a stellate morphology to an elongated morphology, said molecule being Tenacin C; and

b) providing to said cell a nucleic acid [delivery system] encoding a heterologous protein or polypeptide for the transfection of said cell, whereby the presence of said molecule increases the efficiency of delivery of said [a] nucleic acid to said cell when compared to cells transfected in the absence of said molecule [is enhanced].

3. (Amended) The method of claim 1, wherein the nucleic acid encoding said heterologous protein or polypeptide is cloned in a [delivery system] vector which is provided to said cell simultaneously with providing said [agent] molecule.

4. (Amended) The method of claim 1, wherein said nucleic acid encoding said heterologous protein or polypeptide is cloned in a [delivery system] vector which is provided to said cell prior to providing said [agent] molecule.

5. (Amended) The method of claim 1, wherein said nucleic acid encoding said heterologous protein or polypeptide is cloned in a [delivery system] vector which is provided to said cell after providing said [agent] molecule.

27. (Amended) A composition for enhancing the efficiency of delivery of a nucleic acid to a cell, said composition comprising

a) tenascin C [n agent] [capable of enhancing the cytoskeletal permissiveness of said cell for transfection in an amount effective to enhance said permissiveness] which cause the morphology of a cell to change from a stellate morphology to an elongated morphology; and

b) a nucleic acid [delivery system] encoding a heterologous protein or polypeptide for the transfection of said cell.

28. (Amended) The composition of claim 27, wherein said nucleic acid encoding said heterologous protein or polypeptide is cloned into a [delivery system] vector which is selected from the group consisting of a plasmid vector, a viral vector and a linearized nucleic acid.

33. (Amended) A kit for enhancing the efficiency of delivery of a nucleic acid to a cell, said kit comprising

a) an instructional material;

b) [an agent capable of enhancing the cytoskeletal permissiveness of a cell for transfection in an amount effective to enhance said permissiveness] tenascin C which causes morphology of a cell to change from a stellate morphology to an elongated morphology; and

c) a nucleic acid[delivery system] encoding a heterologous protein or polypeptide for transfection into said cell.